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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,826	09/12/2006	Quanzhi Liu	089210-000100US	1852

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
4161	

MAIL DATE	DELIVERY MODE
09/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,826	LIU ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 11-26* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 14-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 13, 25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/10/2007 and 1/11/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-2 and 11-26 are currently pending. Claims 11-12 and 14-24 are withdrawn. Claims 3-10 are cancelled. Accordingly, claims 1-2, 13 and 25-26 are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Information Disclosure Statement

2. All references have been considered.

Priority

3. The earliest effective filing date afforded the instantly claimed invention has been determined to be 06/04/2004 as to claims 1-2, 13 and 25-26.

Election/Restrictions

1. Applicant's election of Group I in the reply filed on 09/04/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. The requirement is thus deemed proper and is therefore made FINAL.

5. Applicant further elected the species wherein M is Na^+. The elected species reads upon claims 1-2, 13 and 25-26.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of cardio-cerebral ischemic diseases, does not reasonably provide enablement for their prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

6. While Applicant has enabled a method of treating cardio-cerebral ischemic diseases, in the sense that Applicant enables a method for reducing conditions associated with that disease in humans suffering from that condition, curing and preventing the disease are not considered enabled. Accordingly, claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diseases (conditions or disorders) as discussed, does not reasonably provide enablement for the prevention of such diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

7. Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered, with the most relevant factors discussed below.

8. Nature of the invention: The nature of the invention is determined in part by the state of the prior art. Even a cursory perusal of the teachings of the medicinal arts reveals that they have not advanced to the point where complex conditions such as, inter alia, cardio-cerebral ischemic diseases can in any way be said to be preventable. The art, in general, teaches, instead, that what may in some cases be prevented with regard to such diseases or disorders are their associated symptoms.

9. Breadth of the claims: The claims are broad in that they claim a method for preventing cardio-cerebral ischemic diseases, the breadth of which exacerbates the complexity of the invention.

10. Guidance of the specification/The existence of working examples: The amount of direction provided by the Applicant is considered to be determined by the specification and the working examples. Applicant's data do not demonstrate that the instant invention is capable of preventing any disease or disorder.

11. State of the art/Predictability of the art: The level of predictability in the art is considered to be relatively low. The basis of all modern medicine and biology is, of course, chemistry. Yet even under the best of circumstances, and several hundred years after Lavoisier laid the foundations of its modern practice, chemistry remains and experimental science. Neither the medicinal/biological arts nor the chemical arts upon which they are based have advanced to the point where certainty has replaced the need for clinical and/or laboratory experimentation.

12. Amount of experimentation necessary: Regardless of the amount of experimentation involved, Applicant's claim with respect to the prevention of numerous

and various diseases and disorders enumerated in the specification is not believable in light of the present understanding in contemporary medicinal arts. It is settled case law that allegations of utility that are not believable in light of contemporary knowledge in the art must be substantiated by acceptable evidence or stricken from the specification. *In re Ferns*, 163 USPQ 609 (CCPA 1969); *Ex Parte Moore*, 129 USPQ 8 (BPAI 1960); *In re Hozumi*, 226 USPQ 353 (Comr. Dec 1985); MPEP 706.03(n) and 706.03(z).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

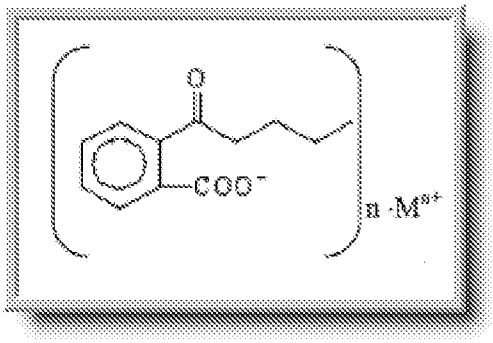
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. **Claims 1-2, 13 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Yang et al* (CN 1382682) (provided by Applicant) published on 12/04/2002 for which US 2005/0288263 is being used as the English language translation, and in further view of *Berge et al* (J Pharm Sci 66(1):1-19, 1977).**

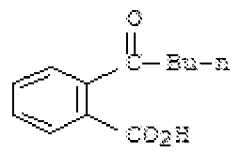
17. Instant claims 1-2 and 13 are drawn to compounds having the formula



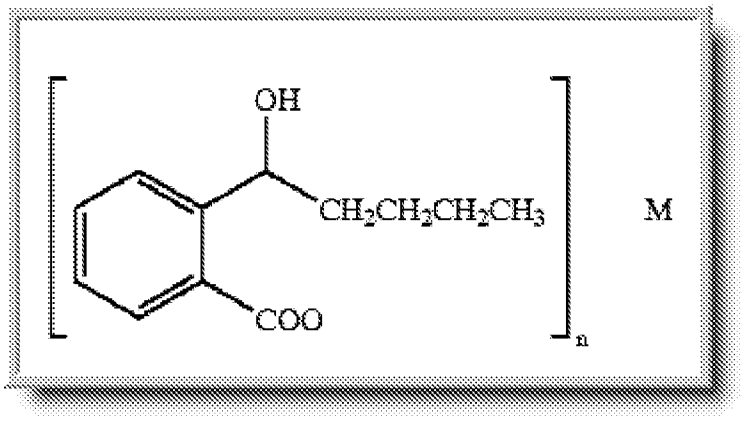
wherein n is 1 or 2 and M is elected as the monovalent metal ion Na^+ which encompasses the compound 2-(α-n-pentanonyl)benzoate. As evidenced by the following STN document, 2-(α-n-pentanonyl)benzoic acid (STN Registry Number 550-37-8) is well known in the

art:

RN 550-37-8 REGISTRY
ED Entered STN: 16 Nov 1984
CN Benzoic acid, 2-(1-oxopentyl)- (CA INDEX NAME)
OTHER CA INDEX NAMES:
CN Benzoic acid, o-valeryl- (8CI)
OTHER NAMES:
CN 2-Pentanoylbenzoic acid
CN 2-Valerylbenzoic acid
CN Ligusticumic acid
CN o-Valerylbenzoic acid
MF C12 H14 O3
CI COM
LC STN Files: BEILSTEIN*, CA, CAPLUS, CASREACT, CHEMCATS, CSCHEM, MAPRALERT, TOXCENTER, USPATFULL
(*File contains numerically searchable property data)



18. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate the sodium salt of 2-(α-n-pentanonyl)benzoic acid, which is taught by STN Registry Number 550-37-8, to result in the instant compound. As taught by *Berge et al*, “The chemical, biological, physical, and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form" (Page 1, Column 1, Paragraph 1). More specifically, *Berge et al* teach sodium as a potentially useful salt form approved by the FDA (Page 2, Table 1). Furthermore, *Yang et al* specifically teach the structurally and functionally related

compound  wherein n is 1 and M is the monovalent metal ion Na^+. Accordingly, it would have been obvious to a person of ordinary skill in the art to use the formulate the sodium salt of 2-(α-n-pentanonyl)benzoic acid in view of *Berge et al* - which provide a motivation to form salts forms of chemical compounds and which teach sodium as an acceptable salt form - and in view of Yang et al – which teach the sodium salt form of structurally and functionally related compounds.

19. Instant claims 25 and 26 are drawn to the compound of claim 1 for the treatment of cardio-cerebral ischemic diseases, etc and one or more pharmaceutically acceptable carrier (claim 25), in the form of a tablet, capsule, granule, etc (claim 26). *Yang et al* specifically teach that structurally similar 2-(α-hydroxypentyl)benzoates are useful in the "treatment of diseases such as cardioischemia, cerebroischemia, heart and brain arterial occlusions, etc" (Paragraph 0001). A person of ordinary skill in the art at the time the invention was made, recognizing the similarity in structure between the instant compounds and the compounds taught by *Yang et al*, would have expected the compounds would have similar properties and would have been motivated to use the compounds for the treatment of conditions taught by *Yang et al* with a reasonable expectation of success. Furthermore, *Yang et al* teach that “the pharmaceutical

composition of the present invention comprises a treatment effective amount of the compound of the present invention as an active ingredient and a pharmaceutically acceptable carrier" (Paragraph 0027). Additionally, *Yang et al* teach administration of the pharmaceutical formulation “in the dosage form such as tablets, particles, or capsules” (Paragraph 0030). Accordingly, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to formulate a pharmaceutical composition comprising 2-(α-n-pentanonyl)benzoate as an active ingredient and a pharmaceutically acceptable carrier, in the dosage form of a tablet (for example) to treat diseases such as cardio-cerebral ischemic diseases.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571)270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Patrick Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 4161

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161